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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------|---------------------|------------------|
| 09/380,825      | 09/07/1999  | DWAYNE THOMAS FRIESEN | PC9835AJTJ          | 3116             |

7590 01/29/2003  
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EXAMINER

WARE, TODD

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/380,825 | <b>Applicant(s)</b><br>FRIESEN ET AL. |  |
|                              | <b>Examiner</b><br>Todd D Ware       | <b>Art Unit</b><br>1615               |  |
|                              |                                      |                                       |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on 04 November 2002.

2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 1-67 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-67 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
       Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
       If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
       a) ☒ All    b) ☐ Some \*    c) ☐ None of:  
           1. ☒ Certified copies of the priority documents have been received.  
           2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
           3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
       \* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
       a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)<br>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)<br>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____<br>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)<br>6) <input type="checkbox"/> Other: _____ |
|--|---|

### **DETAILED ACTION**

Receipt of amendment filed 11-4-02 is acknowledged. Claims 1, 7, 10, 13, 15, 20, 22, 29 have been amended and new claims 30-67 have been added as requested. Claims 1-67 are pending.

#### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Welch, Jr. et al (4,536,518; hereafter '518).
3. '518 discloses sertraline and sertraline salts (see C 2, L 54-58) compositions that are the same as the instant claims. For solubilizing agents, see column 7, line 22- column 8, line 22. Products of identical chemical composition can not have mutually exclusive properties. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.

#### ***Response to Arguments***

4. Applicant's arguments filed 11-4-02 as applied to the amended and newly added claims have been fully considered but they are not persuasive. Applicant argues that the instant claims are directed to highly soluble salt forms of sertraline not disclosed in '518. This argument is not found persuasive since not all the claims are directed to the

particular salt forms (see at least claims 22-29 for example) and also because '518 sets forth the salt forms specified by Applicant in column 2, lines 54-58.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Welch, Jr. et al (4,536,518; hereafter '518).

7. '518 teaches sertraline and sertraline salts (see C 2, L 54-58) compositions that are the same as the instant claims. For solubilizing agents, see column 7, line 22- column 8, line 22. '518 does not specifically teach inclusion of an organic acid as a solubilizer in the taught embodiments, however '518 does teach inclusion of salts that dissolve in solution to form organic acids (e.g. sodium citrate) as excipients (i.e. fillers or carriers). Therefore, it is the position of the Examiner that it would have been obvious to one skilled in the art at the time of the invention to adjust the amount of salt in accordance to the size of the desired tablet with the motivation of producing a tablet having desired handling and swallowability characteristics. Furthermore, combination of excipients would have been obvious to one skilled in the art at the time of the invention with the motivation that an amount of one excipient necessary may not be available so as to necessitate inclusion of an amount of another excipient (e.g. calcium carbonate) in the formulation.

***Response to Arguments***

8. Applicant's arguments filed 11-4-02 as applied to the amended and newly added claims have been fully considered but they are not persuasive. Applicant argues that the instant claims are directed to highly soluble salt forms of sertraline not disclosed in '518. This argument is not found persuasive since not all the claims are directed to the particular salt forms (see at least claims 22-29 for example) and also because '518 sets forth the salt forms specified by Applicant in column 2, lines 54-58. Applicant further argues that '518 does not teach the inclusion of an organic acid. Applicant admits recognition that '518 teaches organic acids salts such as sodium citrate and argues that since these salts lack acidic functionality, they would not be expected to provide as much concentration enhancement as that provided by the organic acids. However, the instant claims are not limited accordingly and Applicant has not provided data supporting this assertion. It is noted that the instant specification does provide some probative evidence for increased solubility for sertraline, however this evidence is not in accordance with Applicant's statements and is also not commensurate in scope with the claims.

***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw  
January 25, 2003

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600